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VACCINE SAFETY - NOVARTIS VACCINE

Earlier this week six European countries stopped the use of two Novartis flu vaccines because of protein particles seen in certain batches, but the company says the aggregates are harmless. Italy and Switzerland suspended sales of Fludax and Agrippal on Oct 24, and Austria, France, Germany, and Spain [subsequently followed suit](#). The vaccines are not sold in the United States. In an Oct 26 statement, [Novartis voiced](#) confidence in the safety and efficacy of the two vaccines, which are made in Italy. "To date, data from the ongoing seasonal vaccination campaign have shown no unexpected adverse events," the company said.

On Wednesday, October 31 both Canada and Switzerland [resumed distribution](#) of the Novartis vaccines. Health Canada said it based the clearance decision on tests and a risk assessment, along with reviews from European partners and from Novartis. None of the data pointed to a safety issue, [according to the statement](#).

The Centers for Disease Control and Prevention (CDC) released key points related to this situation (included on Page 2.)

FLU VACCINE AND HEART DISEASE

- [Does the flu shot curb heart disease?](#)
- [Influenza Vaccine May Reduce Risk of Heart Disease and Death](#)

INFLUENZA RELATED JOURNAL ARTICLES

There are multiple articles on influenza vaccine effectiveness in the recent edition of [Epidemiology and Infection](#).

- [Molecular evidence for interspecies transmission of H3N2pM/H3N2v influenza A viruses at an Ohio agricultural fair, July 2012](#)
- [Evaluation of the specificity and sensitivity of a potential rapid influenza screening system](#)
- [Adjuvants in influenza vaccines](#)
- [The economic value of a quadrivalent versus trivalent influenza vaccine](#)

INFLUENZA NEWS ARTICLES

- [EMA: Evidence Insufficient to Link Flu Shot With Narcolepsy](#)
- [Incentives Prompt High Health Worker Flu Vaccine Acceptance](#)
- [Flu shots for health care workers stir debate](#)
- [Scientists Move Closer to a Lasting Flu Vaccine](#)

RAPID INFLUENZA TESTS

This week's [Morbidity and Mortality Weekly Report](#) (MMWR) evaluates 11 commercially available rapid influenza diagnostic tests (RIDTs) used in the United States. The study found that most RIDTs detected viral antigens in samples with the highest influenza virus concentrations, but detection varied by virus type and subtype at lower concentrations. Clinicians should be aware of the variability of RIDTs when interpreting negative results and should collect test samples using methods that can maximize the concentration of virus antigen in the sample.

INFLUENZA IN MICHIGAN

On Monday October 29, 2012, MDCH [held a press conference](#) with Michigan Osteopathic Association and Michigan State Medical Society on the importance of influenza and pertussis vaccines.

Related News Articles: [Michiganders urged to get whooping cough, flu vaccines](#)

[Doctors Seeing Big Rise in Flu and Whooping Cough](#)

INFLUENZA SURVEILLANCE

This the CDC [released a report](#) on the wide range of influenza programs they work with international partners on to build capacity to respond to pandemic influenza and to prevent and control seasonal influenza.

FLU RESOURCES

Stay up-to-date with:

MDCH: www.michigan.gov/flu

CDC: www.cdc.gov/flu

HHS: www.flu.gov

Check out the [MDCH Flu Gallery](#) for posters you can use this flu season.

FLU VACCINES REQUIRED TO BE ENTERED INTO MCIR

As a reminder, providers are required to report ALL immunizations, including flu, administered to every child born after December 31, 1993 and less than 20 years of age within 72 hours of administration into the [Michigan Care Improvement Registry \(MCIR\)](#). Please ensure you are entering your doses for adults as well!

FluBytes is distributed to MDCH flu partners for informational and communication purposes. Please feel free to distribute widely. Archived editions of FluBytes can be found [here](#). To access archived editions of MI FluFocus click [here](#).

I got my flu vaccine. Have you got yours?

CDC'S KEY MESSAGES ON NOVARTIS VACCINE SAFETY:

- Recently, Novartis voluntarily provided the Italian health authorities with its assessments supporting the quality, efficacy and safety of two seasonal influenza vaccines, Agrippal and Fluad, produced at Novartis site in Italy.
- As precaution, Italian ministry of health temporarily halted distribution of Agrippal and Fluad, following a report by Novartis of small particles in a batch of these vaccines. This batch of vaccines was not released for distribution.
- The particles are formed by proteins essential to the vaccine manufacturing process. The protein aggregation (clumping) can naturally occur in vaccines in very small quantities.
- Novartis confirms the safety and efficacy of these vaccines are not impacted by the presence of protein aggregates. There is no contamination of the vaccine. The vaccine has passed all sterility testing.
- The two vaccines that are the subject of the voluntary recall, Agrippal and Fluad, are not licensed in the United States and are not distributed in the United States.
- FDA has licensed two Novartis influenza vaccines for use in the United States, Fluvirin and Agriflu.
- FDA has not received reports of problems with Fluvirin. Agriflu is not available in the U.S. for the 2012-13 season.
- FDA and CDC closely monitor the safety of influenza vaccines, and no problems have been detected with the vaccines that are currently in use for the U.S. public.
- Current information about influenza vaccine lots that have been released by FDA for the U.S. public can be found [here](#).
- For further information about this voluntary recall, please visit the manufacturer website, which is updated regularly with new information: <http://www.novartisvaccines.com/fluinfo/>